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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO
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08/988, 292 12/10/97 THEEUWES

F ARC-2600-R1

EXAMINER

QM32/0911

RODRIGUEZ, C

ART UNIT

PAPER NUMBER

OWEN J. BATES  
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3763

DATE MAILED:

09/11/01

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**BEST AVAILABLE COPY**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	08/988,292	THEEUWES ET AL.	
<b>Period for Reply</b>	Examiner	Art Unit	
	Cris L. Rodriguez	3763	
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>02 July 2001</u> .			
2a) <input checked="" type="checkbox"/> This action is FINAL.                    2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-8, 10-21 and 23-30</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input checked="" type="checkbox"/> Claim(s) <u>23-27 and 30</u> is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1-5, 8, 10-12, 14, 15, 18-21, 28 and 29</u> is/are rejected.			
7) <input checked="" type="checkbox"/> Claim(s) <u>6, 7, 13, 16, 17,</u> is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		6) <input type="checkbox"/> Other: _____	

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 10, 11, 14, 15, 18-20, 28 and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lerner et al(2,922,425).

Lerner et al discloses an applicator or dispensing device comprising, see figure 4, a member 12, a plurality of protrusions 14 extending from the first surface, and a connecting medium 16.

3. Claims 1, 8, 10, 11, 18-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kellet et al(5,261,426).

Kellet et al discloses an applicator comprising a member 6, a plurality of protrusions 5 extending from the first surface, and a connecting medium 1. See response to arguments below.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al in view of Gerstel et al(3,964,482).

Lerner et al discloses an applicator or dispensing device comprising the elements substantially as claimed. However, Lerner et al does not disclose the protrusion comprising blades.

Gerstel et al teaches a drug delivery device having puncturing protrusions(col 7 lines 32-37) for the piercing the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lerner et al by providing the puncturing protrusion as shown by Gerstel et al in order to introduce an agent to a body surface. See response to arguments below.

#### *Response to Arguments*

6. Applicant's arguments filed January 25, 2001 have been fully considered but they are not persuasive.

In response to applicant's argument that "the protrusions are capable of penetrating the body surface", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the

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intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, Applicant haven't set forth what body surface is being capable of piercing or penetrating.. An example of a body surface could be a plastic film. Also, the claims are not limited to the medical art.

***Allowable Subject Matter***

7. Claims 6, 7, 13, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. Claims 23-27 and 30 are allowable over the prior art of record.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on M-F from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, Richard Seidel can be reached on (703) 308-5115. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*Cris 9/10/01*  
Cris L. Rodriguez

September 10, 2001



RICHARD K. SEIDEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700